ImageChecker® D

User Manual

Software Versions 8.1–8.3

PN 14375 Rev 001

Earlier. Smarter. Better.™

Mammography

ImageChecker® D CAD Server

User Manual

Software Versions 8.1–8.3

PN 14375 Rev 001

Earlier. Smarter. Better.™

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MergeCOM-3 Advanced Integrator's Tool Kit is a product of Merge Healthcare.

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Part 1: Introduction

- 1.1. Intended Use
- 1.2. Available Resources
- 1.3. Warnings and Cautions

The ImageChecker D CAD Server uses R2 Technology's Gold-Standard CAD (computer-aided detection) software to analyze mammography images. The CAD results, when viewed with mammography images on a workstation, are used to assist in the detection of regions of the breast that may be cancerous. The system is not a diagnostic device; radiologists can interpret only original mammograms.

1.1. Intended Use

The ImageChecker system is a computer system intended to identify and mark regions of interest on routine screening and diagnostic mammograms to bring them to the attention of the radiologist after the initial reading has been completed. Thus, the system assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.

1.2. Available Resources

The following resources are available when working with ImageChecker D.

- **Technical Support and Service:** For contact information, see 'Technical Support' on the back of the title page of this manual.
- **User Manual:** This user manual describes the use of ImageChecker D in a simple, streamlined format. You can purchase additional copies of the user manual through your R2 Technology Account Manager.
- **Customer Bulletins:** R2 Technology is committed to making our products safe and easy to use. If an issue arises or new features become available, you will receive a Customer Bulletin.
- **Training:** The R2 Technology Applications team is available to train your staff, should you feel they need additional training. Contact your R2 Technology Account Manager if you want personalized instruction.

⚠ ***Note:*** *If you purchased the ImageChecker D system directly from an FFDM manufacturer or distributor, your technical support and training will be provided by them.*

1.3. Warnings and Cautions

Radiological Interpretation

- The radiologist should base interpretation only on the original images and not depend on the CAD marks for interpretation.
- The device is a detection aid, not an interpretative aid. The CAD marks should be activated only after the first reading.
- The device does not enhance what the user sees, rather it helps to identify regions on mammograms that should be re-examined.
- The device marks calcification features with triangles (Calc marks) and mass features with asterisks (Mass marks). Where mass and calcification features overlap within a specified distance (10-mm default), the device marks overlapping features with pointed crosses (Malc marks). These features may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device.
- EmphaSize (variable-size) marks – Some sites may choose to display prominence detail, in which case the size of a Calc, Mass, or Malc mark is proportional to the ranking of the feature by the algorithm. The marked features may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device. For more information, see '4.3. EmphaSize (Variable-Size) Marks'.
- During routine interpretation of mammograms and CAD marks created by ImageChecker D, R2 Technology recommends use of a mammography workstation that has been FDA-approved, recently calibrated, and employs a CAD marking schema authorized by R2 Technology.
- The use of digitized images (scanned film images) for primary reading has not been approved by MQSA. Digitized film images retrieved from archive should be used only for the purpose of comparison with digital images meeting the current standard.
- The device does not identify all areas that are suspicious for cancer.

  – Some lesions are not marked by the device and a user should not be dissuaded from working up a finding if the device fails to mark that site.

  – The device is not designed to detect changes from other mammograms.

  – The device is not designed to detect skin thickening or nipple retractions.

  – Conditions of the breast that diminish mammographic sensitivity, such as density of normal tissue, also diminish the sensitivity of the device.

  – The device is more sensitive for detection of calcifications than masses, and the sensitivity depends on the site-specific operating points chosen. For sensitivity values, see '4.8. Operating Points'. In addition to not marking all masses, the algorithm has a lower sensitivity for masses greater than 2.5 cm in diameter.

  – Individual practice patterns may influence results obtained when using this device. Therefore, each facility and radiologist should carefully monitor the results

that this device has on their practice of mammography in order to optimize its effectiveness.

- Safety and effectiveness have not been established for analyzing mammograms from patients with breast implants. For patients with breast implants, only Implant-Displaced Views can be processed by the system and only in cases with a maximum of 2.5 cm (1 in) of the breast implant appearing on the image.
- The performance of the system has not been characterized for special diagnostic views (e.g., magnified views or spot-compressed views). Process only full-view diagnostic images.
- The performance of the system has not been characterized for segmented views of the breast (e.g., 'mosaic' views) where there is not a clear breast border. Process only views with breast borders.
- Superolateral to Inferomedial Oblique (SIO) and From Below (FB) views are not supported by ImageChecker systems when using the GE Radiotherapy Structure Set (RTSS) CAD format. These views will be processed, but the results will be flipped for the Right FB, Left FB, and Left SIO views, and so should not be used for the SIO and FB views when using the GE RTSS CAD format.

System Operation

- Operators should review this manual and receive training before using the system.
- Use the system only outside the patient environment. The system is rated for use only in an office environment.
- For proper system operation, the technical quality of the original films or images (e.g., contrast) should meet relevant MQSA standards or the appropriate national standards and be acceptable to the mammographer.
- The symbol next to the power connector indicates a potential shock hazard. To reduce the likelihood of electrical shock or fire hazard, connect the computer only to a power receptacle that is properly grounded and provides voltage and current within the specifications of the system.
- There is a small risk of electrostatic discharge (static electricity). It is mostly a nuisance and not likely to cause harm. However, a shock can cause accidental injury, if, for example, you suddenly withdraw your arm and hit it against something. To minimize possibility of shock, maintain greater than 40% relative humidity, use shoes with natural-material soles, place equipment on nonpolymer floors such as concrete, wood or floors treated with static dissipative, and/or routinely touch metal with a metal object, such as a key, to painlessly discharge the charge from your body.
- Do not place liquid containers on the device. In the event of a spill, shut down power to all components prior to cleaning to minimize the possibility of electrical shock. If internal components are exposed to liquid, do not operate the device – contact your service representative.
- Always shut down the computer according to the procedures provided in this manual. Improper system shutdown can cause loss of data or damage to the computer operating system.

- The device design and mode of operation are consistent with current standard mammography clinical practices, as governed by the requirements of the Mammography Quality Standards Act (MQSA) of 1992. Users are advised to comply with the MQSA for the United States, or the appropriate national standards, when implementing the ImageChecker Mammography System in clinical protocols.
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at her or his own expense.

Installation and Maintenance

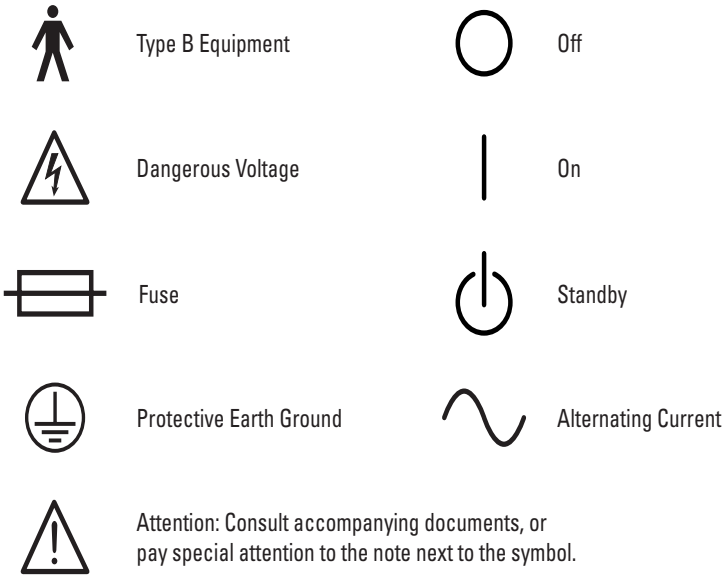
This product contains no user-serviceable parts. To prevent damage to the system:

- Maintain equipment in a well-ventilated, air-conditioned environment.
- Do not install or repair the ImageChecker D system. Only trained personnel, authorized by R2 Technology, are qualified to install or repair the system.
- Disconnect power cord before moving or servicing.
- Before cleaning the computer, always shut down the system according to the shutdown procedures in this manual and disconnect the power cord to prevent the possibility of electrical shock. Never use alcohol, benzene, thinner, or other flammable cleaning agents.
- Never use a two-prong adapter or extension cord to connect primary power to the system. Use of a two-prong adapter disconnects the utility ground and creates a severe shock hazard.

For service training, contact your technical service representative or call R2 Technology Technical Support (see 'Technical Support' on the back of the title page of this manual).

Symbols Used

The following internationally recognized symbols may be used in this manual and on the ImageChecker products.



Common Symbols

Part 2: System Description

- 2.1. Overview
- 2.2. CAD with ImageChecker D
- 2.3. Benefits of CAD
- 2.4. Clinical Workflow
- 2.5. System Features
- 2.6. DICOM Connectivity

2.1. Overview

The ImageChecker Mammography System is the first FDA-approved computer-aided detection (CAD) system for full-view diagnostic and screening mammograms. ImageChecker D is a server computer equipped with software that identifies and marks regions of interest on routine diagnostic and screening mammograms that may warrant a second review by the radiologist. Its purpose is to help minimize observational oversights.

After the radiologist completes the initial reading of the mammogram, he or she views the regions of interest marked on the images, and then returns to the original mammogram for additional review if necessary.

Note that ImageChecker D is not a diagnostic device. Radiologists should base their interpretation only on the original mammogram images.

2.2. CAD with ImageChecker D

The ImageChecker D system is a CAD server equipped with software that analyzes images. The system accepts images from a digital mammography device or archive, and then analyzes the images using a proprietary algorithm (i.e., a set of criteria) that identifies regions of interest. These regions include:

- Clusters of bright spots, which are regions suggestive of calcification clusters
- Dense regions with or without radiating lines, which are regions suggestive of masses or architectural distortions

ImageChecker D generates CAD marks identifying the regions of interest, and sends the marks for display on a digital review workstation. The system can also send the digital images and results to an archive system.

The original digital mammograms for a specific case are displayed on the workstation for review by the radiologist. After making an initial interpretation from the original mammograms, the radiologist displays the CAD marks and chooses whether or not to reinspect the marked regions on the original mammogram.

The ImageChecker algorithm marks certain regions based on their image characteristics. The system marks visually perceptible structures that have some of the generally accepted geometric characteristics of calcifications or masses. The marked areas may be something other than an actual abnormality, but the radiologist generally recognizes that upon a second review of the original mammogram.

For more information about the CAD marks and the ImageChecker algorithm, see 'Part 4: Algorithm Description'.

2.3. Benefits of CAD

The interpretation of mammograms is challenging. Normal breast tissue varies widely among women, even for the same woman over time or at different times of the month. The radiologist also has to balance the need for accurate detection with the need to limit the number of unnecessary procedures. The combination of viewing a large number of cases, radiologist fatigue, the complex image of the breast structure, and the subtle nature of certain observable characteristics of the disease can result in false-negative readings. Studies show that half of undetected cancers are missed due to observational oversights. The prevalence of observational oversights is not strongly related to experience and may be inevitable with human observers.

The ImageChecker Mammography System is like a spellchecker for medical images. It is designed to help radiologists in reducing the number of false-negative readings due to observational oversight by drawing their attention to areas that may warrant a second review.

Retrospective clinical studies using the *film*-based ImageChecker CAD algorithm have shown that use of the ImageChecker system could result in earlier detection of up to 23% of the cancers currently detected with screening mammography in those women who had a prior screening mammogram 9–24 months earlier. Early detection is the key to higher survival rates, better prognosis and lower treatment costs.

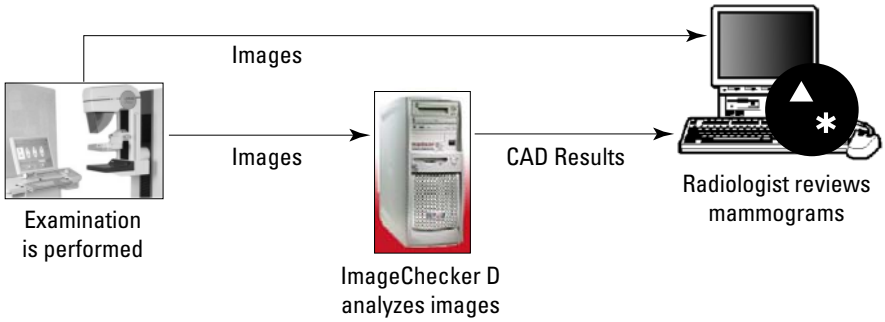
2.4. Clinical Workflow

The ImageChecker D system uses a high-performance computer that can be located in any non-patient environment, provided it is connected to the mammography network. The computer is a CAD server that that receives and processes DICOM-conformant images and supports up to four digital inputs. Sites with full-field digital mammography (FFDM) systems can integrate ImageChecker D into their network and view R2 Technology CAD results on their review workstations. Once configured, little direct interaction with ImageChecker D is necessary. Any interaction is through a user-friendly web browser interface.

ImageChecker D integrates easily into the clinical workflow. Following a mammography examination, the acquisition workstation sends digital images to the review workstation as well as to the ImageChecker D system, which then analyzes the images and sends the CAD results to the review workstation(s).

The radiologist reviews the original mammograms for a patient as he or she normally would. At that point, the radiologist views the R2 Technology CAD results to determine if any area on the original mammogram warrants further review.

After viewing the CAD results and performing any additional review, the radiologist finishes the reading as he or she normally would.



Workflow with ImageChecker D

⚠ ***Note:*** *With all review workstations (except those from Fischer Imaging), you can also send 'for processing' images from the review workstation back to ImageChecker D for analysis. (ImageChecker D can also process 'for presentation' images produced by GE Senographe systems.) You might do this if the image was not analyzed when sent by the acquisition workstation, for example, in the event that ImageChecker D was unavailable for processing at that time.*

2.5. System Features

The system features are determined by the licensed options selected by each site.

ImageChecker CAD Algorithm

The ImageChecker base license provides R2 Technology's Gold Standard CAD algorithm, which provides the medical-imaging industry's highest sensitivity at any given false-mark rate. The algorithm offers three operating points to accommodate differing radiologist preferences. The performance of the system for each of the three operating points as measured on R2 Technology's *film* database is summarized in the following table:

Operating Point	2	1	0
Calcification Sensitivity	97%	96%	95%
Mass Sensitivity	90%	88%	83%
False Marks per Case	2.0	1.5	1.0

When your system is installed, you can select different operating points for calcifications and masses. For more information, see 'Part 4: Algorithm Description'.

Advanced License Features

ImageChecker mammography systems include optional licensed features, allowing you to invest only in the features you want, as well as add features at a later date. The following features can be obtained by purchasing the appropriate license:

- EmphaSize
- PeerView Digital
- Up to four digital input ports (each port is licensed to a specific detector)

⚠ ***Note:*** *Some mammography workstations do not provide certain features such as EmphaSize and PeerView Digital. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

EmphaSize (Variable-Size Marks)

If your site has licensed the optional EmphaSize feature, the review workstation can display variable-size marks that correlate to feature significance. When the algorithm determines that a region is more significant, the CAD mark appears larger, indicating that the region should receive more emphasis from the radiologist. EmphaSize is designed to draw the radiologist's attention to those regions containing mammographic features the algorithm deems to be more indicative of malignancy. For details, see '4.3. EmphaSize (Variable-Size) Marks'.

PeerView Digital

PeerView Digital is an optional software feature available on some review workstations that enables the radiologist to better understand why a region of interest was marked. When activated, PeerView Digital displays a close-up, high-resolution section of the image and highlights physical features found by the algorithm. For details, see '4.4. PeerView Digital'.

2.6. DICOM Connectivity

This section describes image specifications and data formats passed between ImageChecker D and other devices that may be installed at your site. For a more detailed description of the image and CAD results output formats, refer to the *ImageChecker D DICOM Conformance Statement.*

Supported Views and Image Specifications

While the ImageChecker algorithm works under a variety of conditions, it works better with better images. R2 Technology recommends that you obtain mammograms according to the relevant standards for your country, such as the Mammography Quality Standards Act (MQSA) of 1992 in the USA.

The four standard views are:

- LCC – Left Cranio-caudal
- RCC – Right Cranio-caudal
- LMLO – Left Medio-lateral Oblique
- RMLO – Right Medio-lateral Oblique

ImageChecker D supports the following views and view modifiers:

Supported Views	ACR-BIRADS* Equivalent
Medio-lateral	ML
Medio-lateral Oblique	MLO
Latero-medial	LM
Latero-medial Oblique	LMO
Cranio-caudal	CC
Caudo-cranial (from below)	FB
Superolateral to Inferomedial Oblique	SIO
Exaggerated Cranio-caudal	XCC
Cranio-caudal Exaggerated Laterally	XCCL
Cranio-caudal Exaggerated Medially	XCCM

* American College of Radiology Breast Imaging Reporting and Data System

Supported View Modifiers	ACR-BIRADS Equivalent	View Modified
Axillary Tail	AT	MLO
Rolled Lateral	…RL	Any
Rolled Medial	…RM	Any
Implant Displaced*	ID	Any
Tangential	TAN	Any

* Implant-displaced views with a maximum of 2.5 cm (1 in) of implant imaged.

ImageChecker D does not support the following view modifiers:

Unsupported View Modifiers	ACR-BIRADS Equivalent	View Modified
Cleavage	CV	CC
Magnification	M…	Any
Spot Compression	S	Any

In addition, ImageChecker D does not support segmented breast views (e.g., mosaics where there is no clear breast border). ImageChecker D accepts but does not analyze these unsupported views.

Supported Workstation Vendors

Acquisition Workstation/Gantry Devices

ImageChecker D conforms to the DICOM (Digital Imaging and Communications in Medicine) standard. You can configure up to four (4) digital inputs for each ImageChecker system. Each digital port is licensed to a specific detector.

ImageChecker D supports digital mammography x-ray images sent from FFDM acquisition workstation/gantry devices. With the exception of GE images, ImageChecker D supports only 'for processing' images. For GE images, it supports both 'for processing' and 'for presentation' images.

The list of supported devices is given below.

Software Version 8.1

- Agfa-Gevaert Group (Embrace DR – product for use outside the U.S. only)
- GE Medical Systems (Senographe 2000D and Senographe DS)
- Hologic, Inc., including LORAD and Fischer (SenoScan, Selenia)
- Siemens Medical Solutions (MAMMOMAT Novation DR)

Software Version 8.2

- All of the devices supported by v8.1, and
- GE Medical Systems (Senographe Essential)

Software Version 8.3

- All of the devices supported by v8.2, and
- Fujifilm (ClearView-1*m*, ClearView-CS*m*)

Review Workstations

- GE Medical Systems (FFDM review workstation)
- Hologic, Inc., including LORAD and Fischer (SecurView)
- Siemens Medical Solutions (MammoReport Plus)

Archiving CAD Marks

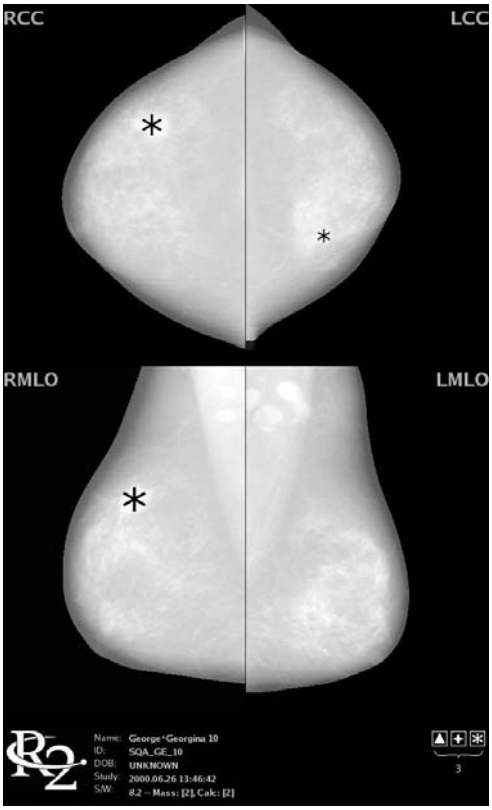
R2 Technology enables users to archive all CAD marks in either the Mammography CAD SR or Secondary Capture formats. If CAD marks are not archived, they can be recreated at a later time if the 'for processing' images have been archived. In addition, the marks can be recreated at a later time from archived 'for presentation' images produced by GE Senographe systems.

In most cases, the same CAD marks should be generated each time the digital images are reprocessed. If the ImageChecker software has been upgraded to a newer version since the images were first processed, then the newer algorithm may produce different CAD marks.

CAD Results Formats

ImageChecker D can be configured to send CAD results in the following formats:

- **Mammography CAD SR** (Structured Report) offers the best review workflow. Most dedicated mammography workstations display the Mammography CAD SR format as overlays on the underlying images. With certain advanced mammography workstations, radiologists can work with CAD results interactively. PACS-based workstations often do not support Mammography CAD SR.
- **Mammography CAD SC** (Secondary Capture) is accepted by all DICOM-conformant products. Mammography CAD SC most closely emulates R2 Technology CAD workflow in film-screen mammography, and is an acceptable substitute when Mammography CAD SR is not supported. When installed, ImageChecker D can be configured to produce Mammography CAD SC images with the four views (see below) in the order required by the clinic (CC above MLO or MLO above CC, R then L or L then R).



R2 Technology CAD SC Result

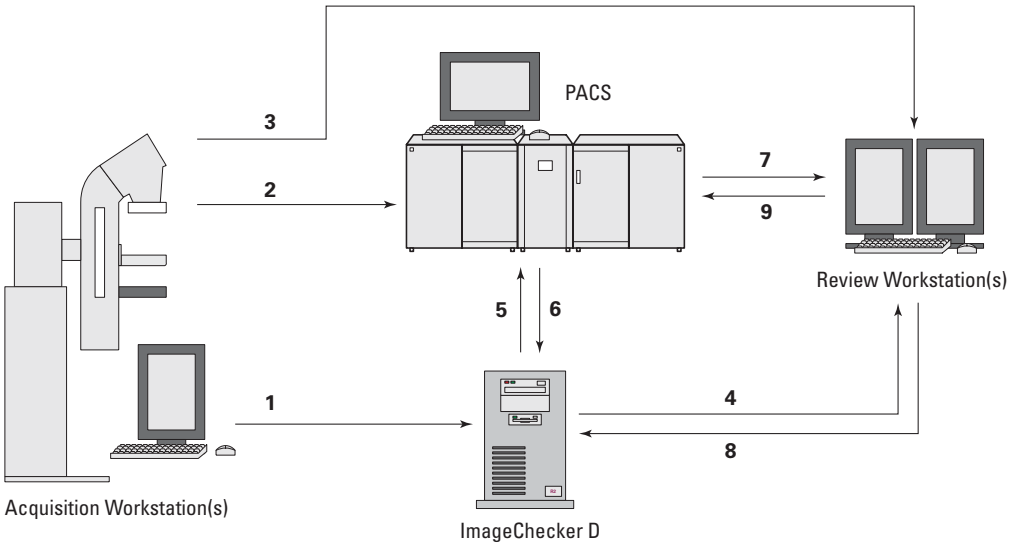
- **RTSS** (Radiotherapy Structure Set) is a format that R2 Technology provides specifically for GE review workstations. This object should not be stored to PACS.
- **PostScript** for paper printout (see 3.3. Printing Results and Reports).

Other Outputs

ImageChecker D can also be configured to output the R2 RightView image format. RightView images are generated only from GE 'for processing' images and are for use with the Citra Mammography Applications Suite.

System Data Flow

The diagram below illustrates the data flow between ImageChecker D and other devices that may be installed at your site. Following is a description of the characteristics, such as configuration and compatibility of the system devices and the data flow among them.



Acquisition Workstations

1, 2, 3: The acquisition workstation can be configured to send digital mammography x-ray images from one of the supported vendors listed on page 12 to any DICOM-conformant device – e.g., ImageChecker D, a PACS archive, and/or a review workstation.

ImageChecker D

4, 5: ImageChecker D can be configured to send CAD results processed from digital mammography x-ray images (and/or the images themselves) to one or more of the following output devices simultaneously:

- PACS
- Review workstation
- Printer (not shown in the previous illustration)
- Any DICOM-conformant device (not shown in the previous illustration)

When installing ImageChecker D, the R2 Technology Service Representative identifies the output devices and configures what output (i.e., digital mammography x-ray images and/or CAD results) will be sent to what device, and for CAD results, in what format.

Typically, review workstations support the Mammography CAD SR CAD results format. If the review workstation does not, then ImageChecker D should send CAD results in the Secondary Capture format (or RTSS, for GE review workstations).

In addition, the PACS device may or may not support the Mammography CAD SR CAD results format. If it does not, and your site wants to archive CAD results, the results should be sent from ImageChecker D in the Secondary Capture format.

If your site does *not* have a PACS, the files (digital mammography x-ray and/or CAD results) can be archived using any adequate storage media. The general workflow remains the same.

PACS

6, 7: The PACS device can be configured to send:

- Digital mammography x-ray images to ImageChecker D (6), which processes and distributes the images according to its configuration, and/or
- CAD results and/or digital mammography x-ray images to the review workstations (7).

Review Workstation(s)

8, 9: The review workstation(s) can be configured to send:

- Digital mammography x-ray images to ImageChecker D (8), which processes and distributes the images according to its configuration, and/or
- CAD results and/or digital mammography x-ray images to the PACS for archiving (9).

Part 3: System Operation

- 3.1. General Usage Guidelines
- 3.2. Displaying CAD Results
- 3.3. Printing Results and Reports
- 3.4. System Shutdown and Startup
- 3.5. Using Queue Manager

3.1. General Usage Guidelines

Once configured, little direct interaction with ImageChecker D is necessary. Any interaction with ImageChecker D is through a web browser and a user-friendly interface.

ImageChecker D analyzes digital mammograms that conform to the DICOM (Digital Imaging and Communications in Medicine) standard. ImageChecker D accepts the images automatically as they are sent from the acquisition workstation or archiving device. If there is a processing error, a message is usually displayed on the acquisition workstation. The order in which you acquire and send the views does not matter. ImageChecker D reads the information stored with each image in the DICOM header and processes the image appropriately.

You can also send 'for processing' ('raw') images from all review workstations (except those from Fischer Imaging) back to ImageChecker D for analysis. In addition, ImageChecker D can process 'for presentation' images produced by the GE Senographe systems. (You might process images sent by the review workstation if the images were not analyzed when originally sent by the acquisition workstation, e.g., in the unlikely event that ImageChecker D was down at that time.)

For proper system operation, ensure that you understand these principles and follow these usage guidelines:

- You can send a maximum of 12 images (any combination of views) together in one case.
- ImageChecker D groups successive images with the same study ID into a case if the images are received within a time-out period configured by the service representative upon system installation. The system also assumes that any image received after the time-out period is from a different study. For more information, refer to the *ImageChecker C/D Service Manual*.
- If there is more than one of the same view in one study (e.g., three RCCs), ImageChecker D analyzes the last of the duplicate views. The system assumes there are duplicates because the first image was not satisfactory to the technologist.

- While ImageChecker D analyzes all supported views, for the four standard views (RCC, LCC, RMLO, and LMLO) it further refines the CAD results as described on pages 32–35. If no standard view is sent, the system takes the most appropriate view and sends it to appear on a printer and/or a review workstation as the standard view. For example, if a CC view is not present but there is an XCC present, the XCC view appears in place of the CC view.
- The processing unit analyzes all supported views but prints CAD marks for just the four standard views. If the site has both a printer and a review workstation, the printout shows CAD results only for the four standard views, whereas the review workstation displays the CAD results for all supported views.

It is the service representative's responsibility to set up your system such that the images are sent automatically to ImageChecker D in addition to the review workstation (or for Fischer Imaging, automatically from the review workstation to ImageChecker D and back). For more about the data flow among the various devices, see '2.6. DICOM Connectivity'.

3.2. Displaying CAD Results

To view digital mammograms and activate ImageChecker CAD marks, follow the guidelines of your FFDM manufacturer. The general procedure is as follows:

1. Perform the examination and process the images on the acquisition workstation using your normal clinical protocol.
2. On the review workstation, read the original mammogram images using your normal clinical protocol. Make an initial interpretation.
3. On the review workstation, activate the ImageChecker CAD marks.
4. Review the ImageChecker CAD marks and, if necessary, re-examine the original mammograms.
5. Repeat steps **1**–**4** for each case.

If your site has licensed PeerView Digital, follow your FFDM manufacturer's method of activating the feature.

3.3. Printing Results and Reports

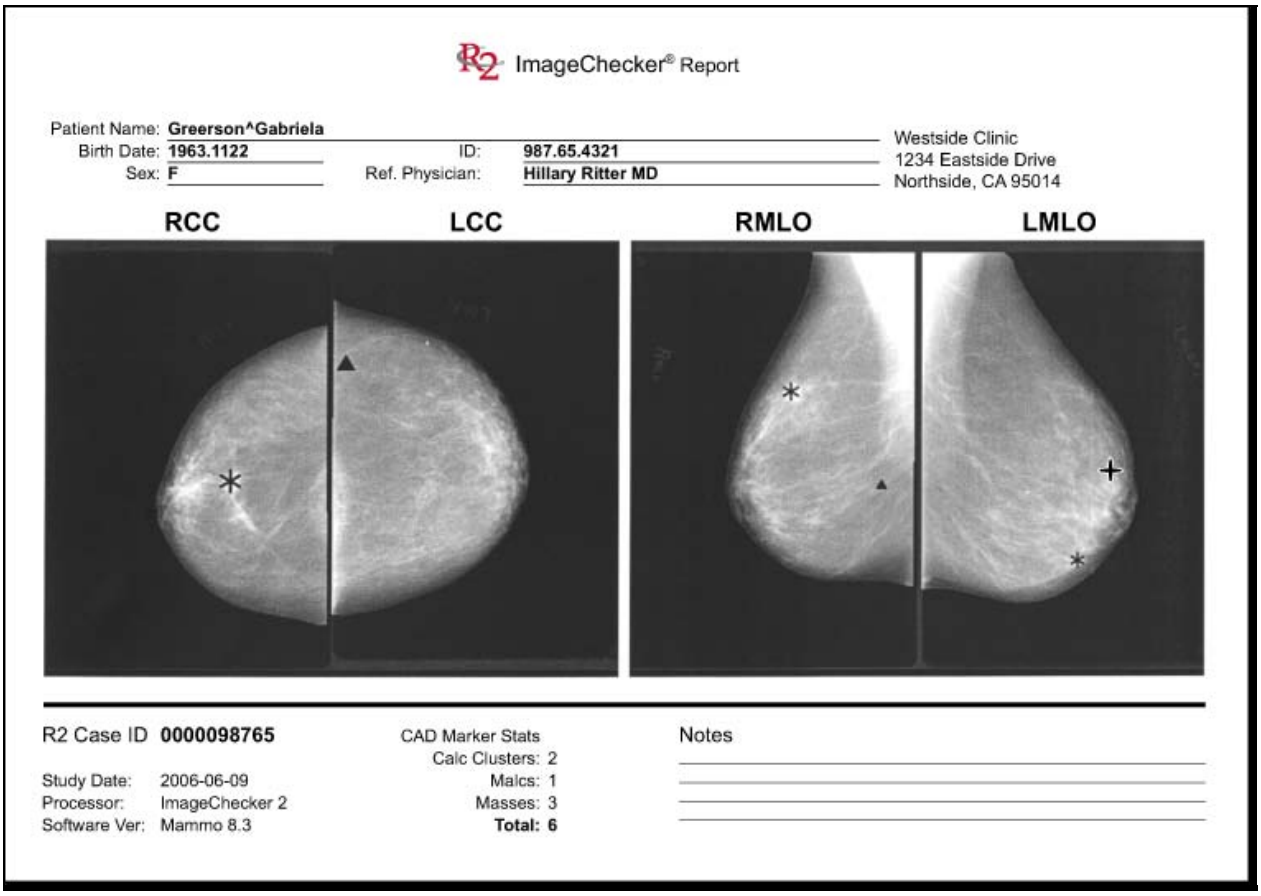
The system provides two printing options:

- Printing CAD Results
- Printing a Reimbursement Report

Printing CAD Results

ImageChecker D can provide printed CAD results for the four standard views if the printing option has been configured by the service engineer. If properly configured, the system automatically prints the results when processing is complete.

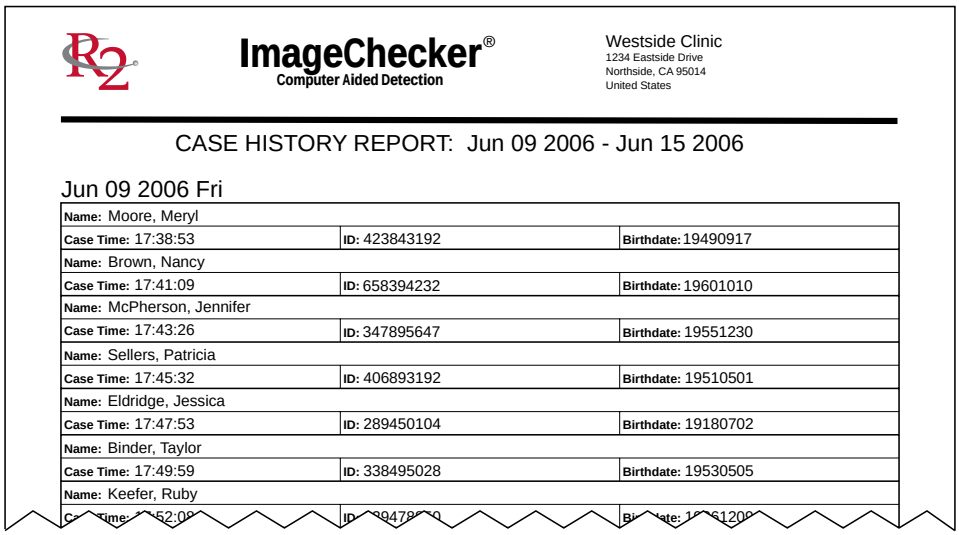
The following is an example of a CAD results printout:



CAD Results Printout

Printing a Reimbursement Report

The Reimbursement Report provides a list of studies processed by ImageChecker D. The system prints a Reimbursement Report automatically on a weekly or monthly basis if this option has been configured by the service engineer. At the end of the report the system reports the total number of cases processed during the interval.



ImageChecker®
Computer Aided Detection

Westside Clinic
1234 Eastside Drive
Northside, CA 95014
United States

CASE HISTORY REPORT: Jun 09 2006 - Jun 15 2006

Jun 09 2006 Fri

Name: Moore, Meryl		
Case Time: 17:38:53	**ID:** 423843192	**Birthdate:** 19490917
Name: Brown, Nancy		
Case Time: 17:41:09	**ID:** 658394232	**Birthdate:** 19601010
Name: McPherson, Jennifer		
Case Time: 17:43:26	**ID:** 347895647	**Birthdate:** 19551230
Name: Sellers, Patricia		
Case Time: 17:45:32	**ID:** 406893192	**Birthdate:** 19510501
Name: Eldridge, Jessica		
Case Time: 17:47:53	**ID:** 289450104	**Birthdate:** 19180702
Name: Binder, Taylor		
Case Time: 17:49:59	**ID:** 338495028	**Birthdate:** 19530505
Name: Keefer, Ruby		

Reimbursement Report

3.4. System Shutdown and Startup

ImageChecker D does not require regular maintenance. The only procedures you might need to perform are:

- Shutting down the system
- Restarting the system (turning off and on again)

For either procedure, you need to know the IP address for the computer. Ask your IT administrator for the ImageChecker D IP address. Write that number here:

ImageChecker D IP Address: _____

Shutting Down the System

You might need to shut down ImageChecker D if you are going to move the computer, or if you know the power is going out for a period of time.

▶ **To shut down the system:**

1. Using a computer that is on the same network as the ImageChecker D computer, open a web browser (e.g., Netscape or Internet Explorer).
2. Type the IP address for ImageChecker D in the address box and press ↵Enter. You do not need to type 'www' or 'http' or anything other than the IP address.
3. At the log-in screen, enter the password: `hOspital` and press ↵Enter. Use lowercase, and the number zero (0) in place of the letter 'o'.
4. Choose 'Shutdown R2 Software and Halt the Unit'.
5. Click OK at the dialog that appears. A bright yellow message is displayed.
6. Click 'Shutdown Now'.
7. Close the browser. The ImageChecker D computer shuts down.
8. Once the computer has shut down, switch it off by pressing the power button. An indicator light indicates whether the computer is on or off.

Restarting the System

You might need to restart ImageChecker D if images are not transferring. Often, restarting the system clears any errors. In some cases, your service representative will ask you to restart the system.

▶ **To restart the system:**

1. Using a computer that is on the same network as the ImageChecker D computer, open a web browser.
2. Type the IP address for ImageChecker D in the address box and press ↵Enter. You do not need to type 'www' or 'http' or anything other than the IP address.
3. At the log-in screen, enter the password `hOspital` and press ↵Enter. Use lowercase letters and the number zero (0) in place of the letter 'o'.
4. Choose 'Restart R2 Software and Reboot the Unit'.
5. Click OK at the dialog that appears. A bright yellow message is displayed.
6. Click 'Reboot Now'. A message appears indicating that the computer is shutting down.
7. Close the browser. The ImageChecker D computer shuts down and restarts automatically.
8. To verify that the system restarted, repeat steps **1**–**2**, then close the browser once the log-in screen appears.

3.5. Using Queue Manager

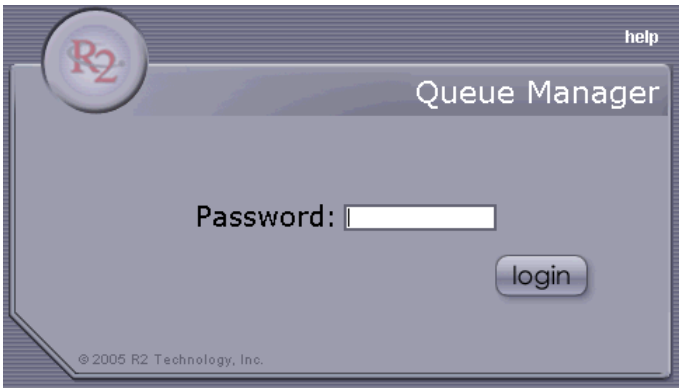
Queue Manager enables you to monitor and manage the queue of cases being processed by ImageChecker D.

▶ To enter Queue Manager

1 Open a web browser on the same network as the ImageChecker computer. In the Address box type the IP address for the computer followed by /qman, and press ↵Enter. For example:

http://10.0.0.10/qman

The browser displays the log-in window.



2 Enter the Queue Manager database password (`hOspital`), and click **login**.

The Queue Manager screen appears, showing the list of cases and the status of each case. Click **Help** at the upper-right corner for detailed instructions.

- Filter the list of cases by entering search criteria in any of the fields in the Search panel at the top of the screen and then clicking the **search** button.
- Sort the list of cases by clicking on any of the column headers. Clicking it again reverses the sort order.
- Click on a patient name to display information associated with the patient in the Description panel at the bottom of the screen.

3 Select one or more cases using the checkboxes on the left side of the queue.

4 Use the **run next**, **delete**, and **stop** buttons to move the selected case(s) to the top of the queue (**run next**), delete them, or stop processing them.

5 When you finish, exit the web browser.

⚠ ***Note:*** *With R2 Technology's mammography products, the Completion (%) field has no function.*

Part 4: Algorithm Description

- 4.1. ImageChecker CAD Algorithm
- 4.2. ImageChecker CAD Marks
- 4.3. EmphaSize (Variable-Size) Marks
- 4.4. PeerView Digital
- 4.5. What the Algorithm Marks
- 4.6. Detecting Calcifications
- 4.7. Detecting Masses
- 4.8. Operating Points

4.1. ImageChecker CAD Algorithm

R2 Technology's Gold Standard CAD algorithm provides the medical-imaging industry's highest sensitivity at any given false-mark rate.

The ImageChecker CAD algorithm looks for characteristics commonly associated with cancer – specifically, calcifications and masses (architectural distortions). The algorithm ranks its findings by likelihood, places marks on those regions above a fixed threshold of likelihood, and then sends the results to the review workstation. The algorithm offers three operating points to accommodate differing radiologist preferences. For more information, see '4.8. Operating Points'.

Due to an ample installed base and a long history with computer-aided detection (CAD), R2 Technology has a large algorithm training database; this means that the algorithm is optimized on a considerable number of cases, and on cases that accurately reflect the population diversity.

4.2. ImageChecker CAD Marks

The ImageChecker D mammography system provides three types of CAD marks. Each mark indicates a region of interest for the radiologist to review. There are two basic types of marks plus one composite mark:

- Calc marks indicate possible calcifications and appear as a triangle.
- Mass marks indicate possible masses/architectural distortions and appear as an asterisk.
- Malc marks are displayed in place of Calc and Mass marks that overlap by a user-specified amount (the default is 10mm), and appear as a pointed cross.

⚠ ***Note:*** *ImageChecker CAD marks may indicate features that do not represent cancer. The skill of the user is required for proper interpretation of features marked by the device.*

The three CAD marks are summarized below.

Calc – Marks regions suggestive of calcifications

Mass – Marks regions suggestive of masses

Malc – Composite mark indicates overlapping Calc and Mass marks (overlap distance is user-specified, default is within 10 mm)

ImageChecker CAD Marks

⚠ ***Note:*** *Some digital mammography workstations cannot display Malc marks. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

For the four standard views (RCC, LCC, RMLO, and LMLO), the system specifies placement of no more than three Calc marks per image, and no more than eight per case; and it specifies placement of no more than two Mass marks per image, and no more than four per case. Since Malc marks are composite marks comprised of overlapping Calc and Mass marks, the maximum number of Malc marks is two per image, and no more than four per case.

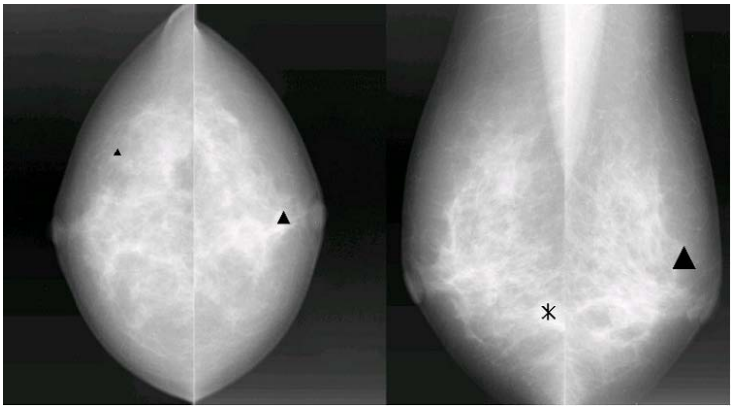
For nonstandard views, the system specifies placement of no more than three Calc marks per image, two Mass marks per image, and two Malc marks per image. The maximum number of marks per case depends upon the number of images in the case (up to 12 images per case).

4.3. EmphaSize (Variable-Size) Marks

The EmphaSize feature provides CAD marks that scale according to feature significance. When a region is more significant, the EmphaSize CAD mark is larger.

As the ImageChecker D evaluates regions of interest, each region is given a ranking. This ranking along with the selected algorithm operating point determines whether or not the region of interest is marked with a CAD mark.

For regions of interest that will be marked, normally the system displays all CAD marks at the same size regardless of ranking. If your site has licensed the optional EmphaSize feature and configured the review workstation to use it, the size of each mark is proportional to its ranking.



Less Important **More Important**

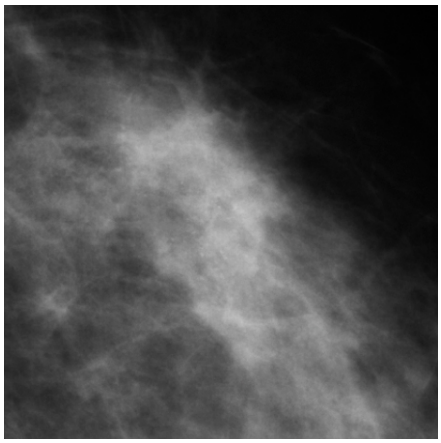
- **Calcifications:** The size of a suspected lesion is of variable significance, since small lesions may be highly significant and large lesions nonactionable. However, there are other key characteristics. For calcifications, the algorithm looks at characteristics such as signal intensity, number of calcifications in a cluster (also referred to as 'cluster density'), shape of the calcifications (i.e., pleomorphism), and other important features to determine lesion significance. As more clinically significant features are found in a suspicious area, the EmphaSize Calc mark becomes larger.
- **Masses**: For masses, the algorithm looks at characteristics such as degree of spiculation, lesion 'shape', contrast to surrounding tissue, texture of lesion interior, edge texture, and other important features which help determine lesion significance. As more clinically significant features are found in a suspicious area, the EmphaSize Mass mark becomes larger.
- **Masses with Calcifications (Malc Marks)**: Regions containing both a mass and calcifications are highly suggestive of malignancy and should be carefully evaluated. As more attributes for calcifications and masses are found in a suspicious area, the EmphaSize Malc mark becomes larger.

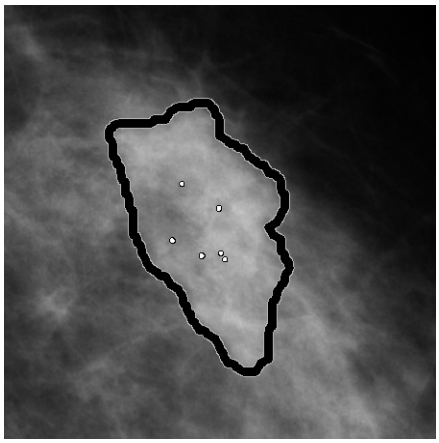
⚠ ***Note:*** *Emphasize and Malc marks are not implemented on all workstations. Refer to your workstation's documentation to determine whether these features are implemented and, if they are, how to use them.*

4.4. PeerView Digital

PeerView Digital provides a high-resolution image of the detected region, highlighting individual calcifications and outlining the central density of each mass. PeerView Digital is a proprietary R2 Technology innovation designed to help the radiologist visualize and analyze the specific features that may indicate malignancy.

- **Calcifications:** PeerView highlights the individual calcifications in the cluster marked by the algorithm. PeerView may not highlight all calcifications in a cluster, but may show additional features suggestive of calcifications that are not highlighted. PeerView generally does not highlight benign calcifications.
- **Masses:** PeerView defines and outlines the central density of the mass so the radiologist can evaluate the margin, shape, and interior characteristics of the CAD-detected mass or distortion. The outline does not generally include spiculations associated with the mass, although the shape of the central density may lead the eye to larger spicules.
- **Masses with Calcifications:** For composite Malc marks, which represent the overlap of one or more Mass and Calc marks, PeerView highlights the calcifications and outlines the central density of the mass and/or distortion found in the CAD analysis. The same region is shown below at left (with no CAD mark) and at right with a PeerView Malc mark (mass with calcifications).





The implementation of PeerView Digital depends on the review workstation. On some review workstations, you activate PeerView by touching the mark on the screen. You toggle the coloring/outline off and on by touching the highlighted area, and deactivate PeerView by touching anywhere outside the PeerView window.

⚠ ***Note:*** *PeerView Digital and Malc marks are not implemented on all workstations. Refer to your workstation's documentation to determine whether these features are implemented and, if they are, how to use them.*

4.5. What the Algorithm Marks

The ImageChecker CAD algorithm searches an image for clusters of bright spots that are suggestive of calcification clusters, for patterns of dense regions, and for dense regions with radiating lines suggestive of masses or architectural distortions.

Calcifications

The algorithm marks:

- Clusters with three or more elements
- Elements that are at or within 3 mm of each other
- Where each element is between 3–150 pixels in size (a pixel is 50 microns by 50 microns in digitized film)

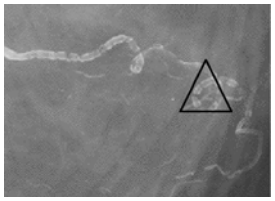
The algorithm does not mark:

- Clusters with fewer than three elements*
- Clusters where each element is separated by more than 3 mm
- Lead skin markers or clips

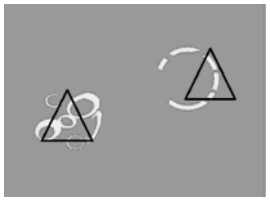
⚠ ***Note:** The algorithm marks two elements if the elements have significant contrast or shape, as defined by the cluster filter. See '4.6. Detecting Calcifications'.*

The algorithm occasionally marks:

- Calcified arteries
- Cluster or rim benign calcifications
- Crossing linear tissues



Calcified Artery

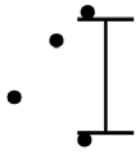


Cluster or Rim
Benign Calcifications

Crossing Linear
Tissues

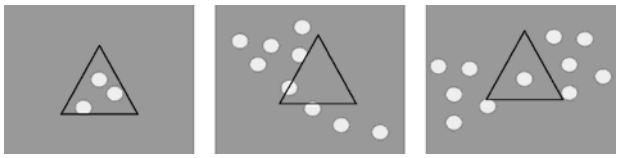
To be considered a cluster, elements need only be at or within 3 mm of another element within the cluster, as shown next:

≤ 3 mm square



Each element is
at or within 3 mm

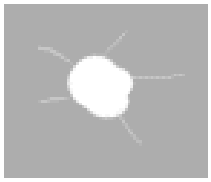
When features in the mammogram meet the generally accepted criteria, the algorithm places a triangular CAD mark over the center of that region (not over a particular element), as is shown next:



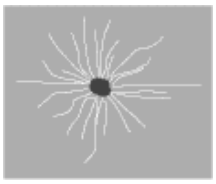
Masses/Architectural Distortions

To detect masses, the algorithm searches the image in a progressive manner looking for circular, dense regions and lines radiating from a common center. The algorithm marks:

- Regions suggestive of masses/architectural distortions
- Dense regions
- Regions with radiating lines



Less pronounced radiating lines but with a central mass



No central mass but pronounced radiating lines

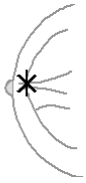
The algorithm does not mark:

- Masses greater than 5 cm in diameter

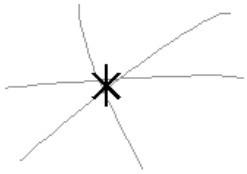
⚠ ***Note:*** *The algorithm usually does not mark masses larger than 2.5 cm. The likelihood of a mass being marked decreases when the mass is larger than 2.5 cm.*

The algorithm occasionally marks:

- Ducts and tissue radiating from the nipple
- Inadvertent crossing of parenchymal tissue
- Well circumscribed masses
- Vague opacities, skin thickening or nipple retraction



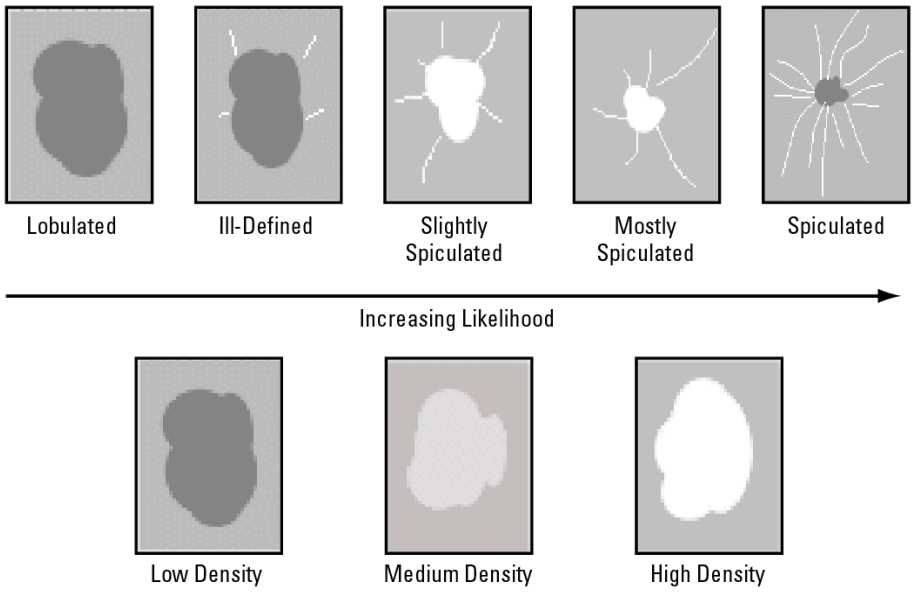
Ducts and tissue radiating from nipple



Inadvertent crossing of parenchymal tissue

The likelihood of a mass/architectural distortion being marked is affected by:

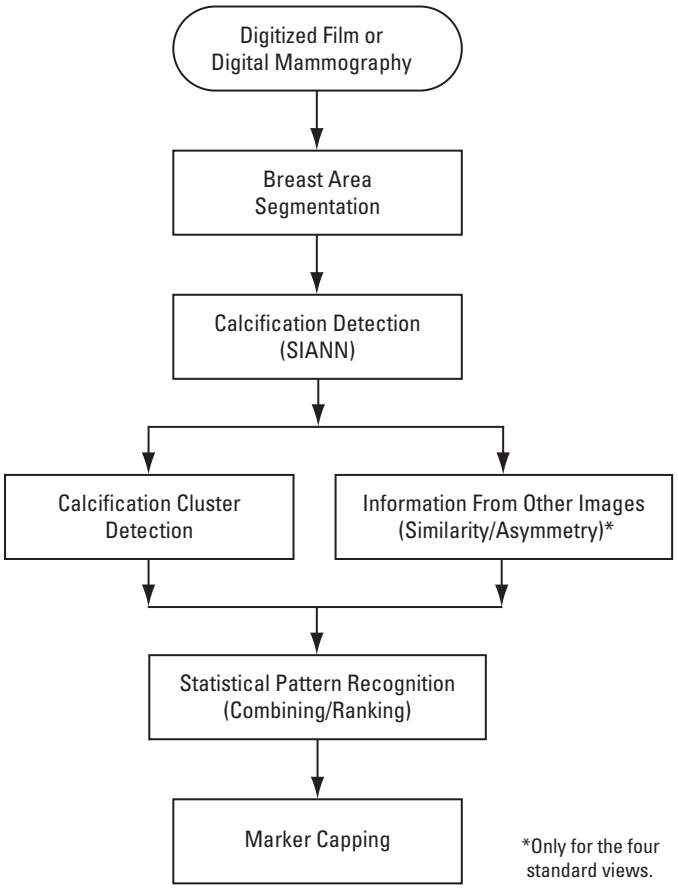
- Margin of the mass (the greater the spiculation, the more likely)
- Degree of density (the higher the density, the more likely)
- Presence of left/right breast asymmetry



When the algorithm finds patterns associated with masses, it places an asterisk at the point of maximum convergence on the image.

4.6. Detecting Calcifications

To detect calcifications, the R2 Technology algorithm performs various analyses.



The algorithm uses two filters (artificial neural networks) to identify the calcifications and their features:

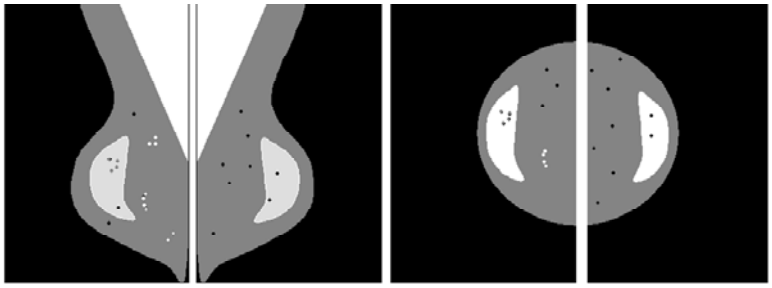
- First, it runs the images through the Shift-Invariant Neural Network (SIANN), a calcification detection filter that has been optimized using R2 Technology's large training database. SIANN is a patented technology developed over 10 years of research at the University of Chicago.
- Then, it analyzes the resulting calcifications using a cluster filter that weights well over a dozen different features, including contrast, shape, and size.

In addition to using these filters to identify the calcification clusters and their features, the algorithm also analyzes:

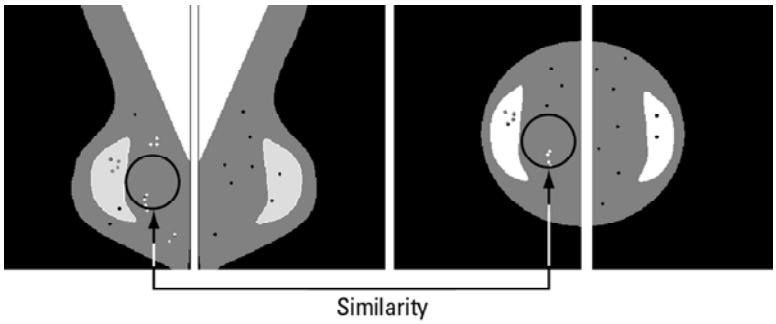
- The location of the cluster within the breast (breast segmentation), and
- Information from other images (only for the four standard views – RCC, LCC, RMLO, and LMLO).

The algorithm then combines the results of these various analyses and employs statistical pattern recognition (against the large training database) to further determine the likelihood of cancer. The end result is a high CAD sensitivity percentage for calcification detection with a low false-positive mark rate.

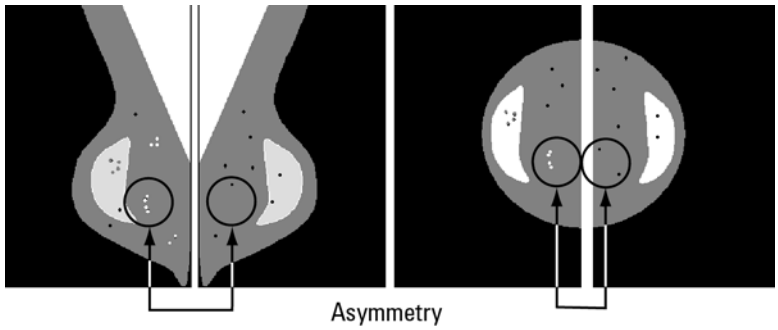
The algorithm accepts the digitized images, segments the breast area and identifies calcification clusters using the SIANN and cluster filters:



The software then compares the views to look for similarity (only for the four standard views – RCC, LCC, RMLO, and LMLO):



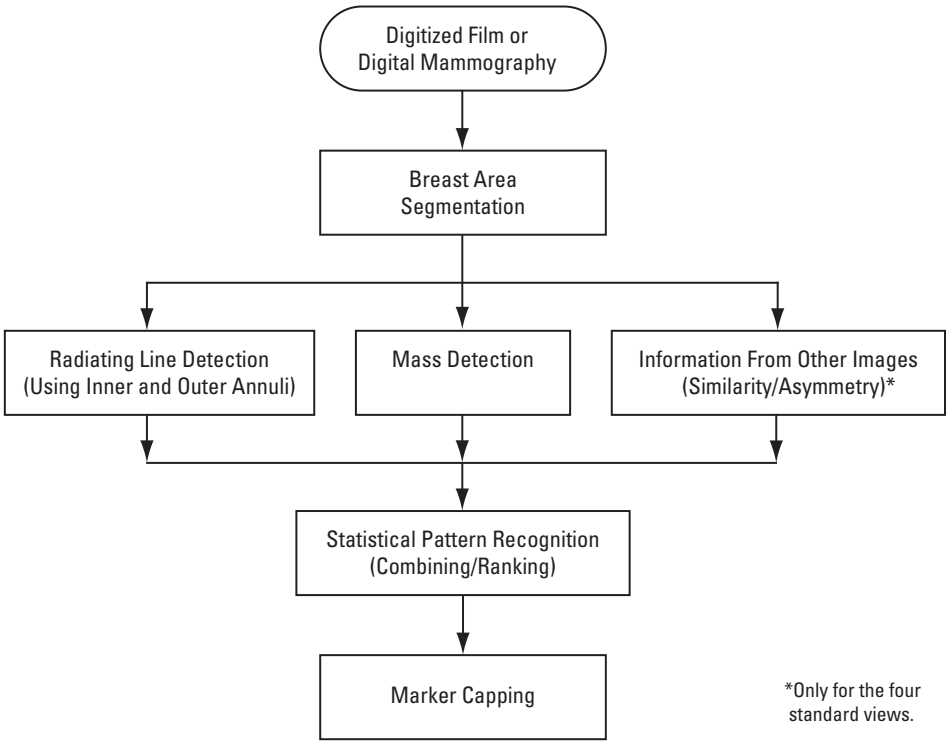
It also looks for asymmetry (only for the four standard views):



The algorithm then runs the resulting cluster and context data against a large training database to determine the ranking for each of the possible clusters. Then, the algorithm either marks or does not mark the clusters, based on the ranking and operating point.

4.7. Detecting Masses

To detect masses, the R2 Technology algorithm performs various analyses.



Using patented technology, the algorithm independently evaluates:

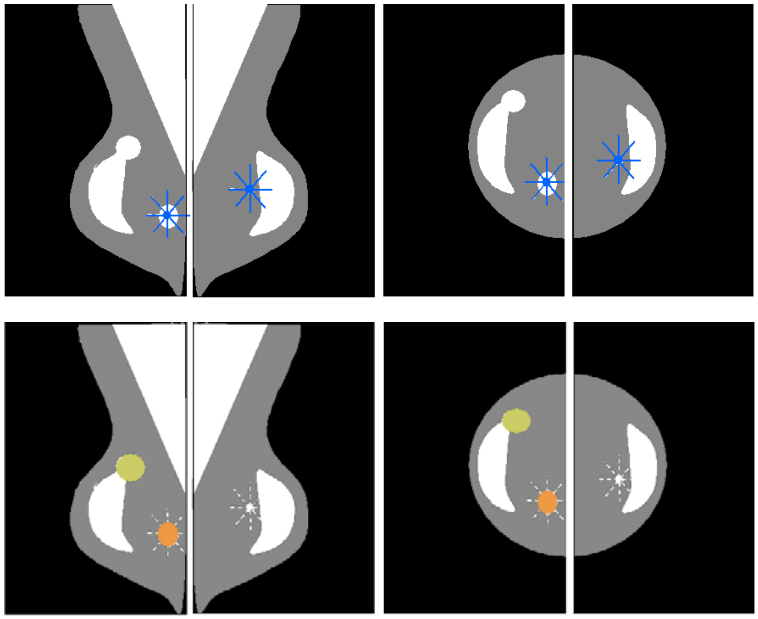
- Presence and degree of spiculation
- Mass density – factors such as density, shape, margin features

In addition to identifying spiculation and mass features, the algorithm also analyzes:

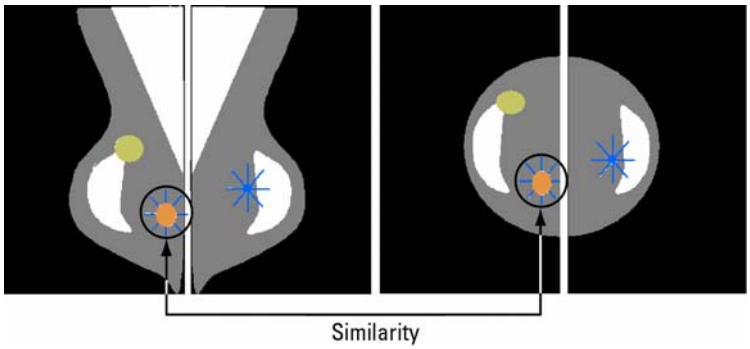
- The anatomy of the breast (breast segmentation), and
- Information from other images (only for the four standard views – RCC, LCC, RMLO, and LMLO)

Finally, the algorithm takes the information from these various analyses and employs statistical pattern recognition (against the large training database) to further determine the likelihood of cancer. The end result is a high CAD-sensitivity percentage for mass detection with a low false-positive mark rate.

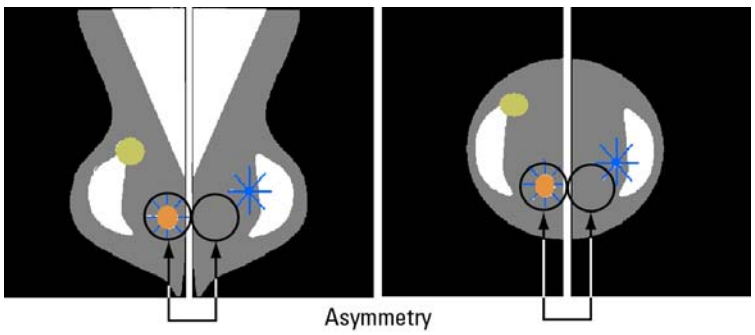
The algorithm accepts the digitized images, segments the breast area and independently identifies radiating lines and masses:



The software then compares the other views to look for similarity (only for the four standard views – RCC, LCC, RMLO, and LMLO):



It also looks for asymmetry (only for the four standard views):



The algorithm then runs the resulting data against a large training database to determine the ranking for each of the possible masses. Finally, the algorithm either marks or does not mark the masses, based on the ranking and operating point.

4.8. Operating Points

ImageChecker Mammography Systems enable each site to choose between three different operating points (i.e., CAD algorithm thresholds): operating point 2, which emphasizes sensitivity, operating point 0, which emphasizes a low false-mark rate, and operating point 1, which is an intermediate point. The table below gives the sensitivity and false-mark rate values for the three operating points for version 8 ImageChecker applications, as measured on R2 Technology's large *film* test database of biopsy-proven malignancies and confirmed normal cases for the four standard views (RCC, LCC, RMLO, and LMLO).

⚠ ***Note:*** *A recent revision to the DICOM standard has resulted in a nomenclature change. The terminology, 'thresholds A, B, and C', used in previous ImageChecker products (software version 8.1 and earlier) has been replaced by 'operating points 2, 1, and 0'. Also note that earlier versions of the ImageChecker application (before version 8) produce slightly different performance results. For further information, see the manuals provided with those systems.*

Operating Point:	2	1	0
Calcification Cases (n = 588)			
Mean Sensitivity[1]	97%	96%	95%
95% Confidence Interval	95.5–98.3%	94.0–97.2%	93.1–96.7%
Mass Cases (n = 767)			
Mean Sensitivity[1]	90%	88%	83%
95% Confidence Interval	87.7–92.0%	85.6–90.2%	79.8–85.2%
Overall (n = 1355)			
Mean Sensitivity[1]	93%	91%	88%
95% Confidence Interval	91.5–94.3%	89.7–92.7%	86.2–90.0%
False-Positive Marks (n = 445)			
Calcification FP/Image[2]	0.16	0.12	0.09
Mass FP/Image[2]	0.35	0.25	0.17
Total False-Positive Marks/Case	2.0	1.5	1.0
Specificity[3] (n = 445)	24.5%	35.1%	48.3%
95% Confidence Interval	20.5–28.5%	30.6–39.5%	43.7–53.0%

1. 'Sensitivity' refers only to the sensitivity of the CAD algorithm, not to the sensitivity of the radiologist using the device.

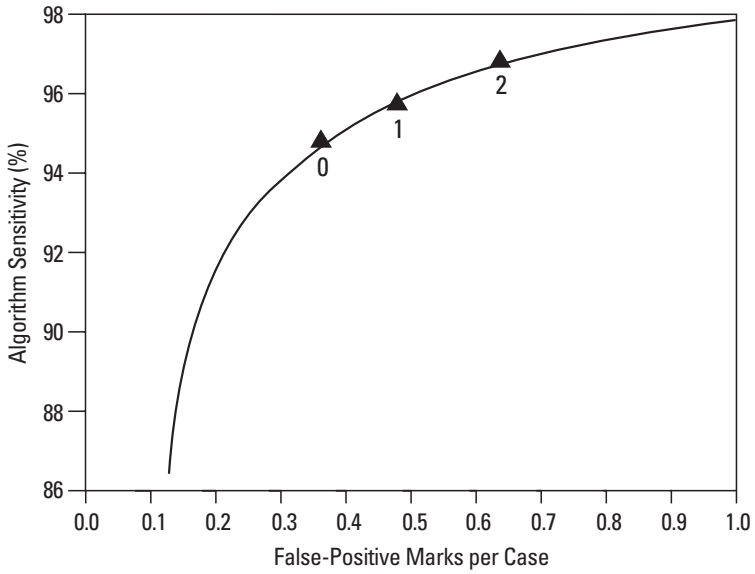
2. 'FP/Image' refers to the average number of false-positive marks per image measured on normal cases.

3. 'Specificity' refers to the percentage of normal cases that, when processed, show no CAD marks.

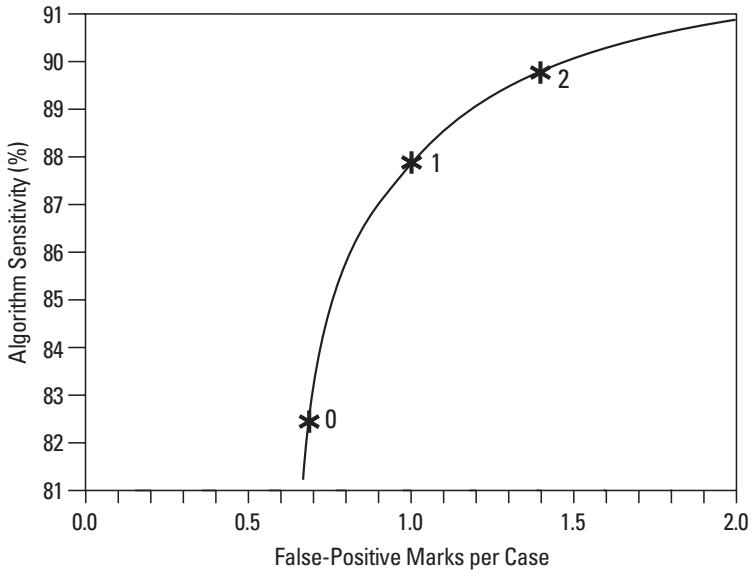
- **Operating point 2** focuses on sensitivity. It gives the best performance for marking regions of interest (i.e., CAD sensitivity), with an accompanying higher false-mark rate. It is suited for sites that want the system to be as sensitive as possible, regardless of the higher false-positive mark rate.
- **Operating point 1** represents an intermediate point. Improvements in the algorithm have allowed points 0 and 2 to be set quite far apart, and R2 Technology believes that some sites may want intermediate behavior from the CAD algorithm.

- **Operating point 0** trades off a lower false-mark rate for a lower overall sensitivity. This operating point is suited for sites that prefer the system to display the fewest false marks.

The following graphs shows plots of algorithm sensitivity vs. false-mark rate with data points for each of the three operating points.



Calcification Performance



Mass Performance

⚠ ***Note:*** *To determine false-mark rates, R2 Technology processes normal screening cases (defined as those with a subsequent normal screening study) through the ImageChecker system and measures the number of false marks per image. More extraordinary screening cases, such as those with additional views, and diagnostic*

studies, may have a very different make-up of images and, as such, may produce results that fall outside the measured normal case mark rate. Since the mark rate is measured per image, a larger number of images in a case should correspond on average with a higher total mark count for that case. However, while clinical experience demonstrates some variation in mark rates, R2 Technology has not found the false-mark rate to vary dramatically when averaged over a large number of cases.

You can choose a different operating point for calcifications than for masses. For example, if you want high sensitivity for calcifications but a moderate balance between sensitivity and false positives for masses, choose operating point 2 for calcifications and operating point 1 for masses.

Each system is shipped with a default set of operating points for both masses and calcifications. You can discuss the choices that are right for your site with your Applications Specialist or, if you would like to change configurations, contact your R2 Technology Technical Service Representative.

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